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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,347	09/25/2001	J. Fernando Bazan	DX0903K1	9754

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DNAX RESEARCH, INC.
LEGAL DEPARTMENT
901 CALIFORNIA AVENUE
PALO ALTO, CA 94304

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/963,347	Applicant(s) BAZAN ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-32 is/are pending in the application.
- 4a) Of the above claim(s) 25-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-24 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 21-24 have been amended as requested in the amendment filed on December 02, 2004. Claims 21-32 are pending in the instant application.

Claims 25-29 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made by original presentation, see section 3 of office action mailed on December 08, 2203

Claims 21-24 and 30-32 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on December 02, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

5. Claims 22-24, as amended, and 30-32 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for those reasons of record in section 6 of Paper mailed on December 08, 2003 and in section 5 of Paper mailed on August 02, 2004. The claim(s) contains subject matter which was not described in the specification in such

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a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant traverses the rejection on the premises that “[t]he present specification describes distinguishing identifying characteristics sufficient to show that Applicants were in possession of the claimed invention” (bottom at page 5 of the Response). Applicant submits that the instant specification discloses full-length sequences of IL-B50 and the structural motifs important for receptor binding. Applicant’s arguments have been fully considered but are not persuasive for the following reasons.

Claims 22-24, as amended, are directed to fragments of a polypeptide of SEQ ID NO: 4 or fragments of polypeptides having 90% identity to the polypeptide of SEQ ID NO: 4, wherein the polypeptide is capable of binding a human IL-B50 receptor. First, nothing in the claims requires that the claimed molecular embodiments are only limited to those sequences that possess specific structures (those alpha helices or motifs characteristic of a member of the short chain cytokines, see bottom at page 5 of the Response). On the contrary, the claims encompass any fragment of the sequence that is structurally related to a particular disclosed sequence. However, the instant specification, as filed, fails to provide written description of even one such fragment, such as a molecular embodiment that lacks the disclosed amino acid sequence of SEQ ID NO: 4 and has any relevance to the instant IL-B50.

6. Claims 22-24 and 30-32 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide encoded by a nucleic acid molecule of SEQ ID NO: 3, does not reasonably provide enablement for any other molecular embodiment structurally related to the polypeptide of SEQ ID NO: 4 for reasons of record in

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section 6 of Paper mailed on August 02, 2004. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant submits that at the time of invention, “recombinant DNA techniques and peptide synthesis had already become routine practice in the relevant field” and, thus, “the relative skill in the relevant art is high” (middle at page 8 of the Response). Applicant further argues that the working examples provide full-length sequences of IL-B50 (bottom at page 8), and that “[t]o practice the claimed invention, a practitioner would prepare variants of IL-B50 based on the sequence information of SEQ Id NO: 2 and SEQ ID NO: 4, and test the activity of these variants to bind the IL-B50 receptor” (top at page 9 of the Response). Applicant’s arguments have been fully considered but are not persuasive for the reasons that follow.

Applicant has taken the position that 35 U.S.C. 112, first paragraph, permits an artisan to present claims of essentially limitless breadth as long as the specification provides one with the ability to test any particular embodiment, which is encompassed by the material limitations of a claim and thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don’t. This argument is not entirely without merit. However, the issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. Applicant’s “make and test” position is inconsistent with the decisions *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988), which was cited as the judicial basis for the instant rejection in the previous office action, and in *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970), which held that

“Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved” (emphasis added).

Claim Rejections - 35 USC § 102

7. Claims 21-24 and 30-32 stand rejected under 35 U.S.C. 102(e) as being anticipated by Sims et al. for those reasons of record in section 11 of Paper mailed on December 08, 2003 and in section 8 of Paper mailed on August 02, 2004.

Applicant argues that because the “318 application asserts that IL-B50 shares similar biological functions with IL-7 [...], and that IL-7 exhibits strong effects on lymphopoietic development and differentiation” then, based on that information, the utility of the claimed IL-B50 molecules is the same as the utility of IL-7 and, further, refers to Utility Examination

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Guidelines “when class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial and credible utility to the assigned protein” (page 11 of the Response). Applicant’s arguments have been carefully considered but are not deemed to be persuasive for the reasons that follow.

As fully explained in the previous communications of record, because the ‘318 application fails to disclose specific utility of IL-B50 (“either stimulatory or inhibitory effect” does not provide for specific activity), and because the specific, substantial and credible utility of the instant IL-B50 is only disclosed in the instant specification, the effective filing date for the instant invention remains the filing date of the instant application, 09/25/2001, which makes “the Sims patent” proper 102(e) reference. Also, the fact that the instant claimed IL-B50 has sequence similarity to the IL-7 class of molecules does not automatically “assign” a specific function to the novel IL-B50. Numerous publications exist on a topic of predicting protein functions from structural similarities or homology to the known proteins. It is well settled in the art that functional characteristics of a protein cannot be unequivocally extrapolated from its structural characteristics. Moreover, in the instant case, because the spectrum of activities of IL-7 is not limited to one single function, there appears to be no real possibility of reasonable prediction which one of IL-7 activities supports the practical utility of the claimed IL-B50.

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original

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signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1646

February 1, 2005